Amendments to the Drawings

FIG. 7 is being amended to delete a line that lacks a reference number.

Attachment: Replacement Sheet
Annotated Marked-Up Drawings

REMARKS

This Reply is organized under appropriate subheadings for the convenience of the Examiner.

Amendments to the Specification

The specification has been amended to provide a description for the longitudinal support member depicted in FIG. 1. No new matter has been added to the specification and entry of these amendments is respectfully requested.

Amendments to Claims 1, 16, 18, 20, 25, and 28

Claims 1, 16, 18, 20, 25 and 28 have been amended to specify that the longitudinal support member is on one side of a plane parallel to and bisecting a longitudinal axis of the graft body and that the longitudinal support member is substantially asymptotic. In addition, independent Claims 16, 18, 20, 25 and 28 have been amended to specify that the longitudinal support member is a curved longitudinal support member that is substantially reverse-mirror symmetrical with respect to a longitudinal axis of a tubular graft body of the device. Support for amendments to Claims 1, 16, 18, 20, 25 and 28 can be found throughout the specification and the originally-filed claims. For example, FIG. 1, and paragraph 0174 of Applicants' published application, describe a longitudinal support member that is curved, parallel to and bisecting a longitudinal axis of a graft body that is substantially reverse-mirror symmetrical with respect to a longitudinal axis of the graft body and has substantially asymptotic ends.

Further, consistent with the Examiner's statement in an Interview Summary dated June 16, 2010, Applicants have amended Claims 1, 16, 18, 20, 25 and 28 to specify that the other side of a plane bisecting a longitudinal axis of the graft body of the claimed vascular repair device is "free of the longitudinal support member." Support for this amendment to the claims can be found in FIG. 1 of the drawings, and in the specification, as amended, with entry of this Reply to the outstanding Office Action. No new matter has been added and Applicants respectfully request entry of these amendments to the claims.

Dependent Claims 70 and 71 have been amended to correct dependencies for canceled claims. No new matter has been added in the amendments to the Claims 1, 16, 18, 20, 25, 28, 71 and 72. Entry of these amendments is respectfully requested.

Advantages of Applicants' Claimed Invention

Applicants' claimed invention, as amended, specifies that the curved longitudinal support member is parallel to and bisects a longitudinal axis of the graph body, has substantially asymptotic ends. The curved longitudinal support member of Applicants vascular repair device is substantially reverse-mirror symmetrical with respect to a centerline of the longitudinal support member. The longitudinal support member causes Applicants' repair device to have columnar strength between individual stents while allowing torsional three-dimensional flexure in direction. In other words, the "S" curve of the longitudinal support allows a "corkscrew" orientation in one direction, but not the other. At the same time, the longitudinal support continues to provide columnar strength that substantially prevents creep of the stent graft during and after implantation within a patient. These advantages of Applicants' invention are further explained in the specification at paragraphs [0171], [0174], [0179], [0187] and [0189]. For example, paragraph [0174] of the specification states:

> [0174] One way to describe the preferred curvature embodiment of the longitudinal support member **40** can be using an analogy of asymptotes. If there are two asymptotes extending parallel to the longitudinal axis **11** of the graft sleeve **10** at the first and second degrees **41, 43** on the graft sleeve **10**, then the proximal portion **42** can approach be on the first degree **41** or extend approximately asymptotically to the first degree **41** and the distal portion **44** can be on the second degree **43**. Because the longitudinal support member **40** is one piece in a preferred embodiment, the curved portion **46** follows the natural curve formed by placing the proximal and distal portions **42, 44** as set forth herein.

Objection of Claims 71 and 72

Claim 71 and 72 were objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim, which was canceled.

Applicants have amended Claims 71 and 72, thereby obviating the rejection.

Objection to the Specification

The Examiner stated the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. In particular, the Examiner stated that correction is required for the limitation that the longitudinal support member is "on one side of a plane bisecting a longitudinal axis of the graft body." In addition, the Examiner stated that the limitation "being free of longitudinal support" was not found in the disclosure of the application.

Applicants have amended the specification to explicitly state that the curved longitudinal support member, as depicted in FIG. 1, includes a longitudinal support member that is "on one side of a plane parallel to and bisecting a longitudinal axis of the graft body" and "free of the longitudinal support member," as suggested by the Examiner in an Interview Summary dated June 16, 2010. Therefore, Applicants' specification, as amended, in view of FIG. 1, provides proper antecedent basis for Applicants' claimed invention.

Rejection of Claims 1-6, 10-14, 16-21, 24-29, 42-48, 51-60, 65-67, 71, 72, 75-77, 80-82, 85-87, 90-92, 95-97 and 110-114 Under 35 U.S.C. §112 Second Paragraph.

Claims 1-6, 10-14, 16-21, 24-29, 42-48, 51-60, 65-67, 71, 72, 75-77, 80-82, 85-87, 90-92, 95-97 and 110-114 were rejected under 35 U.S.C. §112 Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. In particular, the Examiner stated that Claims 1, 16, 18, 20, 25 and 28 include a limitation that the graft body "be free of longitudinal support on the other side of the plane that bisects the longitudinal axis of the graft body that has longitudinal support member on the first side of the plane," and that this limitation is ambiguous. In addition, the Examiner stated it was not clear how it "is possible when the graft body has stents positioned along its longitudinal axis and extend around the circumference that clearly provides support and, thus, establish longitudinal support along the length." The Examiner further stated that claims do not establish how the bisection occurs or what defines "longitudinal support."

Applicants have canceled Claims 3, 5, 17, 19, 29, 42-44 and 46, thereby obviating the rejection of these claims.

As described in paragraphs 0171 and 0172 of Applicants' published application, and as shown in FIG. 1, longitudinal support member 40 provides longitudinal support to Applicants'

vascular repair device. Stents of Applicants' vascular repair device do not provide longitudinal support relative to longitudinal support member 40. As discussed in the interview conducted at the U.S. Patent and Trademark Office on June 16, 2010, and as noted in the Interview Summary of that June 16, 2010 date therewith, the Examiner stated that the phrase "graft body being free of the longitudinal support member" would appear to overcome the rejections of record. In addition, as stated in Applicants' summary of the interview, filed with the U.S. Patent and Trademark Office on July 16, 2010, a limitation in the claims that the curved longitudinal support member is "on one side of a plane parallel to a bisecting" longitudinal axis of the graft body would inherently mean that the other side of the plane parallel to and bisecting the longitudinal axis of the graft body would not include an equivalent longitudinal support member. In other words, an element of claims that the longitudinal support member is on one side means that the longitudinal support member, or its equivalent, cannot be on the other side of a plane bisecting the longitudinal axis of the graft body. Therefore, the claims, as amended, particularly point out and distinctly claim Applicants' invention and, therefore, meet the requirements of 35 U.S.C. § 112, second paragraph.

Rejection of Claims 1-5, 10, 14, 18-21, 24, 25, 27, 43-45, 47, 53, 65-67, 71, 72, 80-82, 85-87, 90-92 and 110-114 Under 35 U.S.C. § 103(a)

Claims 1-5, 10, 14, 18-21, 24, 25, 27, 43-45, 47, 53, 65-67, 71, 72, 80-82, 85-87, 90-92 and 110-114 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsutani *et al.* (EP 1177779) (hereinafter "Matsutani"), in view of Penn *et al.* (U.S. Patent No. 6,183,506) (hereinafter "Penn"). The Examiner stated that Matsutani, specifically FIG. 1, describes a vascular repair device with a structural framework that has at least two pairs of Z-stents having linear profiles in a longitudinal support member 3 that is on one side of a plane bisecting the longitudinal axis of the device and on another side of the plane that is free of the longitudinal support. The Examiner further stated that Penn, specifically FIG. 4, describes a stent support member 370 that can be preformed as a substantially reversed-mirror symmetrical or S-shaped member. The Examiner also stated that Penn teaches a longitudinal support member that need not extend beyond the Z-stents, that Matsutani describes in FIG. 6 stents that have circular-cross section of shapes and that Matsutani discloses a stent graft that can use one longitudinal support

member to only extend to the proximal end of a stent at one end and not its distal end to thereby form a gimbal at one end.

Matsutani describes a stent and a method of making a stent. For example, with reference to FIGs. 1, 3 and 5 and paragraphs 0050 and 0051, Matsutani describes plural vertical wires 3 arranged in an axial direction of master B and connected to wire 1 so as to restrain the portion of wire for master B in an axial direction. Master B, as shown in FIGs. 3 and 5 of Matsutani, is curved to conform to the thoracic aorta, as described in paragraph 0050. The axial direction and bending of wire 1 is wrapped around master B by vertical wires 3. Vertical wires 3 are attached to wire 1 of the stent of Matsutani and are, thus, curved at the proximal end (towards the heart) to conform to master B as shown in FIG. 3.

Vertical wires 3 attached to master B of Matsutani, as noted by the Examiner, are not "reverse-mirror symmetrical," as described by Applicants, for example, in paragraph 0176 of Applicants' published application. In addition, vertical wires 3 of Matsutani do not have substantially asymptotic ends. Further, vertical wire 3 of Matsutani does not include a first degree that is approximately a substantially reverse-mirror image of a portion of vertical wire 3 with respect to a centerline of vertical wire 3. In other words, a portion of vertical wire 3 of Matsutani, when rotated 180 degrees around an axis or orthogonal to the centerline would not overlap with the remaining portion of vertical wire 3, which is required, in order for a longitudinal support member to be considered "reverse-mirror symmetrical," as described by Applicants.

Penn describes expandable stents that include flexure means, as described in Col. 10, lines 53-54, and as depicted in FIGs. 8-10 and 12a-12i of Penn. The flexure means of Penn can include sinusoidal or S-shaped portions, as shown, for example, in FIGs. 12a-12i. Penn, does not remedy the deficiencies of Matsutani, to thereby teach or suggest a longitudinal support member with substantially asymptotic ends that is curved and reverse-mirror symmetrical with respect to a centerline of the longitudinal support member. A curved longitudinal support member with substantially asymptotic ends and reverse-mirror symmetrical, as discussed above, provides a vascular repair device having reduced flexibility at the asymptotic ends relative to the center of the longitudinal support member. The greater flexibility of the longitudinal support member in the center of Applicants' vascular repair device has the advantage of conforming to the greatest

radius of curvature of a vessel, such as a thoracic aorta, while simultaneously providing relatively rigid support at the proximal and distal ends of the vascular support device in an area of lesser curvature of relatively large blood vessel, such as the aorta.

Therefore, Applicants' claimed invention, as amended, meets the requirements of 35 U.S.C. § 103(a) in view of Matsutani, alone, or in combination with Penn.

Rejection of Claims 6, 26, 28, 29, 46, 59 and 95-97 Under 35 U.S.C. § 103(a)

Claim 26, 28, 29, 46, 59 and 95-97 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsutani, in view of Penn and further in view of Robinson *et al.* (WO 98/23242) (hereinafter "Robinson"). The Examiner stated that Robinson teaches a longitudinal support that can be connected to the graft by sutures and, thus, is not a permanent affixation to the structural framework and, therefore, can be considered independent from the structural framework of the vascular repair device. The Examiner stated it would have been obvious to one of skill in the art to use the longitudinal support member free from the framework as taught by Robinson with the stent graft of Matsutani, as modified by Penn, to permit the graft body to freely conform to the curvature of a blood vessel.

Applicants have canceled Claims 29 and 46, thereby obviating the rejection for these claims.

Applicants' claimed invention, as set forth in independent Claim 1, as amended, is directed to a vascular repair device that includes a curved longitudinal support member that is on one side of the plane parallel to and bisecting the longitudinal axis of a graft body that has substantially asymptotic ends. As discussed above, Matsutani, alone or in combination with Penn do not teach or suggest Applicants' claimed invention, as set forth in amended Claim 1.

Robinson does not teach or suggest Applicants' vascular repair device, as set forth in amended independent Claim 1, in view of Matsutani, alone or in combination with Penn. Robinson describes a vascular repair device that includes elongate struts 50 around the entirety of frame 36, not on one side of frame 36, as shown, for example, in FIGs. 6 and 21 of Robinson. In particular, as shown in FIG. 6 and as described at page 14, lines 1-2, the endoprosthetic implant of Robinson includes frame 36 that preferably includes a connection between anchor 28 and stent 40 to form elongate struts 50. As stated by Robinson at page 14, lines 7-10, "the

[elongate] struts 50 should be connected to the anchor 38 and stent 40 in a manner that will reduce the risk of development of stress concentrations on the frame when the device is flexed at any time during its use." According to Robinson, at page 14, lines 5-12, to accomplish reduced development stress concentrations, "the struts 50 may be attached ...by welding to the stent 40 and by sutures 52 that also serve to attach the anchor 38 and stent 40 to graft 22."

Applicants' vascular repair device, as amended, requires that the curved longitudinal support member be on one side of a plane parallel to and bisecting the longitudinal axis, that the longitudinal support member, be reverse-mirror symmetrical relative to the longitudinal axis, and have substantially asymptotic ends. One of skill in the art would not be motivated by the teachings of Matsutani, alone, or in combination with Penn and Robinson to modify the longitudinal support members of Robinson to thereby obtain Applicants' vascular repair device that includes a curved longitudinal support member on one side of a plane parallel to and bisecting a longitudinal axis of the graft body and having asymptotic ends, and reverse-mirror symmetrical relative to the longitudinal axis. Therefore, Claims 6, 29, 28, 59 and 95-97, as amended, meet the requirements of 35 U.S.C. § 103(a) in view of Matsutani, alone or in combination with Penn.

Rejection of Claims 1-13 Under 35 U.S.C. § 103(a)

Claims 11-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsutani, in view of Penn and further in view of Bolea *et al.* (U.S. Patent No. 6,821,291) (hereinafter "Bolea"). The Examiner stated that Bolea describes, at FIG. 22, a stent with a wire member having looped extremities 184 in that the loops can be collapsed to remove the stent device.

Dependent Claims 11-13 further limit amended independent Claim 1 to specify that the longitudinal support member has, respectively, rounded ends, a looped end and two looped ends each with curved longitudinal extremities. As discussed above, Matsutani, alone or in combination with Penn, does not teach or suggest a vascular repair device, as set forth in amended Claim 1, from which Claims 11-13 depend, which require that the curved longitudinal support member have substantially asymptotic ends and is reverse-mirror symmetrical relative to a longitudinal support of a longitudinal axis of the claimed device.

Bolea does not remedy the deficiencies of Matsutani or Penn to teach, or suggest, Applicants' claimed invention. Bolea describes a removable stent system and a method to extract the removable stent system. One of skill in the art would not be motivated by the teachings of Bolea, alone or in combination with Matsutani, to modify the vascular repair device of Penn to include a curved longitudinal support member that is on one side of a plane parallel to and bisecting the longitudinal axis that has substantially asymptotic ends, and is reverse-mirror symmetrical, as claimed by Applicants. Therefore, Applicants' claimed invention as set forth in dependent Claims 11-13, meet the requirements of 35 U.S.C. § 103(a), in view of Matsutani, Penn and Bolea, alone or in any combination.

Rejection of Claim 16, 17, 42, 51 and 75-77 Under 35 U.S.C. § 103(a)

Claim 16, 17, 42, 51 and 75-77 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsutani, in view of Penn and Robinson and Bolea. The Examiner stated that Bolea describes, with reference to FIG. 22, a stent with a wire member having looped extremities 184. The Examiner also stated that Bolea teaches that the loops enable an end to be collapsed to remove the stent device, in side view Col. 10, lines 31-36.

Applicants have canceled Claims 17 and 42, thereby obviating the rejection with respect to these claims. Independent Claim 16, as amended, includes a curved longitudinal support member that has substantially asymptotic ends and is on one side of a plane parallel to and bisecting the longitudinal axis of a graft body, and that the longitudinal support is reverse-mirror symmetrical relative to a longitudinal axis of the claimed device.

As discussed above, Matsutani, Penn, Robinson and Bolea, each alone, or in any combination, do not teach or suggest a vascular repair device that includes a longitudinal support member having substantially asymptotic ends and reverse-mirror symmetrical relative to a longitudinal axis of the device. Therefore, Applicants' claimed invention, as set forth in amended independent Claim 20, and the claims that depend from amended Claim 20, meet the requirements of 35 U.S.C. § 103(a) in view of Matsutani, Penn, Robinson and Bolea, each alone or in any combination.

Rejection of Claims 48, 54, 56 and 58 Under 35 U.S.C. § 103(a)

Claims 48, 54, 56 and 58 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsutani, in view of Penn, and further in view of Hartley *et al.* (U.S. Patent No. 6,524,335) (hereinafter "Hartley"). The Examiner stated that Hartley teaches, and references FIG. 2, a stent graft with distal end 1 having one apex more than another of the stents. The Examiner stated that it would be obvious to one of skill in the art to use stents with at least one more apex than other stents to better anchor the vessel, as described by Hartley, and to incorporate the stent graft of Matsutani, as modified by Penn, to improve the seal against the vessel wall.

Hartley does not remedy the deficiencies of Matsutani, alone or in combination with Penn, to teach or suggest a vascular repair device that includes a curved longitudinal support member on one side of a plane parallel to and dissecting a longitudinal axis of the graft body that has substantially asymptotic ends, and is reverse-mirror symmetrical relative to a longitudinal axis of the device. In particular, Hartley describes a prosthesis that includes stents sutured to graft material. Dependent Claims 48, 54, 56 and 58 depend from independent Claims 1, 18, and 25. As discussed above, one of skill in the art would not be motivated by the teachings of Matsutani, in view of Penn, to modify the vascular repair device of Matsutani, to thereby obtain a vascular repair device that includes the curved longitudinal support member on one side of the plane parallel to and bisecting the longitudinal axis and that has substantially asymptotic ends; nor does it teach a longitudinal support that a reverse-mirror symmetrical relative to a longitudinal axis of the device. Nothing in the teachings of Hartley, would motivate one of skill in the art to further modify the vascular repair device of Matsutani or Penn to thereby obtain Applicants' claimed vascular repair device. Therefore, the subject matter of Claims 48, 54, 56 and 58 meet the requirements of 35 U.S.C. § 103(a) in view of Matsutani, Penn or Hartley, taken separately or in any combination.

Rejection of Claim 60 Under 35 U.S.C. § 103(a)

Claim 60 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsutani in view of Penn and Robinson in further in view of Hartley. The Examiner stated that Hartley teaches, in reference to FIG. 2, a stent graft with distal stent 1 having an apex more than another of the stents.

Claim 60 depends on independent Claim 28, which, as discussed above, includes a curved longitudinal support member having substantially asymptotic ends. As discussed above, Matsutani, alone or in combination with Penn, Robinson or Hartley, in any combination, teach or suggest a vascular repair device that includes a curved longitudinal support member having substantially asymptotic ends and that is substantially reverse-mirror symmetrical with respect to a centerline of the longitudinal axis of the graft body. Therefore, dependent Claim 60, meets the requirements of 35 U.S.C. § 103(a) in view of Matsutani, Penn, Robinson and Hartley, each alone or in any combination.

Rejection of Claim 52 Under 35 U.S.C. § 103(a)

Claim 52 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsutani, in view of Penn, Robinson and Bolea, and further in view of Hartley. The Examiner stated that Hartley, with reference to FIG. 2 teaches a stent graft with distal stent 1 having an apex more than another of the stents.

Claim 52, depends on independent Claim 16, which requires that the vascular repair device include a curved longitudinal support member on one side of the plane parallel to and bisecting the longitudinal axis of the graft body and that has substantially asymptotic ends, and that is reverse-mirror symmetrical relative to the longitudinal axis. As discussed above, one of skill in the art would not be motivated by the teachings of Matsutani, Penn, Robinson, Bolea and Hartley, each alone, or in any combination to modify the vascular repair device of Matsutani to include a curved longitudinal support member on one side of a plane parallel to and bisecting the longitudinal axis of the graft body, and the longitudinal support member having substantially asymptotic ends and being reverse-mirror symmetrical relative to the longitudinal axis. Therefore, Claim 52 meets the requirements of 35 U.S.C. § 103(a), in view of Penn, Robinson, Bolea and Hartley, taken alone or in any combination.

Information Disclosure Statement

A Supplemental Information Disclosure Statement (SIDS) is being filed concurrently herewith. Entry of the SIDS is respectfully requested.

SUMMARY AND CONCLUSIONS

Claim 71 and 72, as amended, are proper dependent claims. The specification provides proper antecedent for the claimed subject matter. Applicants' claimed invention, meets the requirements of 35 U.S.C. § 112, second paragraph. Applicants' claimed invention, as amended, meets the requirements 35 U.S.C. § 103 in view of Matsutani, Penn, Robinson, Bolea and Hartley, each alone or in any combination. As amended, Applicants believe that claims are in condition for allowance and respectfully request reconsideration and withdrawal of all outstanding objections and rejections. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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